INTERVIEW SUMMARY

Claims 1, 2, 4, 5, 7-10, and 13-24 are active in this application.

Applicants wish to thank Examiner Fay for the helpful and courteous discussion with Applicants' Representative on July 7, 2005. The Amendment filed June 9, 2005, was discussed. The Examiner indicated that it appeared that the rejections of the claims for lack of enablement are overcome.

She further pointed out that Serial No. 10/354,083 has now issued as U.S. 6,872,383, and Serial No. 09/926,411 has been allowed on August 25, 2004, and is expected to issue as a patent soon. Accordingly, the Examiner indicated that she would convert the provisional double patenting rejections into regular double patenting rejections.

Applicants traverse the double patenting rejections. None of the claims of U.S. 6,872,383 or Serial No. 09/926,411 disclose or suggest the required Schirmer score or SPK score prior to treatment as claimed in the present application.

With regard to the prior art rejections, the Examiner is likely to withdraw her rejection over Tsubota et al.

Regarding WO/0066122, the Examiner appeared to be willing to at least withdraw the rejections as being anticipated in view of the claim amendments filed June 9, 2005.

Applicants wish to point out that the claims are neither anticipated nor obvious over WO 00/66122 and Peyman (US 6,489,335). WO 00/66122 and Peyman fail to disclose or suggest methods for treating dry eye, ocular discomfort and ocular damage as claimed in which an ophthalmic composition comprising from about 0.01% to about 0.1% of FK506 is administered to a patient who, prior to treatment, has a Schirmer score of less than or equal to seven millimeters per five minutes, or a superficial punctate keratitis (SPK) score of at least two.

The present specification discloses that patients having the claimed score respond well to the treatment of the present invention. That is, those patients have a high sensitivity to a certain concentration of FK 506. For example, the specification discloses at page 4, lines 9-14:

> Moreover, the present inventor has discovered that patients having Schirmer scores less that about 7 to less than about 5 millimeters per five minutes and/or superficial punctuate keratitis scores of greater than or equal to 2 or greater than or equal to 3 respond particularly well to treatment.

In addition, the specification discloses at page 15, line 31 to page 16, line 3:

> Preferred patients are those having a Schirmer score of less than 7 millimeters per five minutes and/or a superficial punctuate keratitis (SPK) score of at least 2. The most responsive patients, however, are those having a Schirmer score of less than 5 millimeters per five minutes and/or an SPK score of at least 3.

Further, the Examples show the following as disclosed at page 17, lines 15-22:

> The results of the lissamine green staining at day 42 showed an improvement over baseline in macrolide-treated patients having a Schirmer score of less than 5 millimeters/five minutes and an SPK score of at least 3. While placebo-treated patients showed decreases of 0.6 ± 3.15 units from baseline, patients treated with 0.01% and 0.06 macrolide compound, showed decreases of 1.8 ± 1.47 units and 3.9 ± 2.03 units, respectively.

In contrast, WO 00/66122 and Peyman do not disclose that patients having the claimed Schirmer score or SPK score are highly sensitive to a specific concentration of FK 506.

Therefore, the rejection of Claims 1-14, 17 and 18 under 35 U.S.C. § 102(b) as anticipated by WO 00/66122, and the rejection of Claims 15, 16 and 19 under 35 U.S.C. § 103(a) as being unpatentable over WO 00/66122 and Peyman (US 6,489,335) are believed to be unsustainable as the present invention is neither anticipated nor obvious and withdrawal of these rejections is respectfully requested.

Applicants respectfully request that the Examiner acknowledge that the references cited in the **Information Disclosure Statement, filed** in the above-identified application on **August 23, 2004,** have been considered.

This application presents allowable subject matter, and the Examiner is kindly requested to pass it to issue. Should the Examiner have any questions regarding the claims or otherwise wish to discuss this case, he is kindly invited to contact Applicants' below-signed representative, who would be happy to provide any assistance deemed necessary in speeding this application to allowance.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon

Kirsten Grueneberg

Kirsten A. Grueneberg, Ph.D.
Registration No.: 47,297

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
NFO:KAG: